

# PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001  
Expiration Date: 02/28/2023

## Use of Human Specimens and/or Data

\* Does any of the proposed research in the application involve human specimens and/or data?  Yes  No

Provide an explanation for any use of human specimens and/or data not considered to be human subjects research.

Add Attachment

Delete Attachment

View Attachment

Please complete the human subjects section of the Research & Related Other Project Information form prior to completing this form.

The following items are taken from the Research & Related Other Project Information form and displayed here for your reference. Any changes to these fields must be made on the Research & Related Other Project Information form and may impact the data items you are required to complete on this form.

Are Human Subjects Involved?

Yes  No

Is the Project Exempt from Federal regulations?

Yes  No

Exemption number:

1  2  3  4  5  6  7  8

## If No to Human Subjects

Skip the rest of the PHS Human Subjects and Clinical Trials Information Form.

## If Yes to Human Subjects

Add a record for each proposed Human Subject Study by selecting 'Add New Study' or 'Add New Delayed Onset Study' as appropriate. Delayed onset studies are those for which there is no well-defined plan for human subject involvement at the time of submission, per agency policies on Delayed Onset Studies. For delayed onset studies, you will provide the study name and a justification for omission of human subjects study information.

## Other Requested Information

Add Attachment

Delete Attachment

View Attachment

[Click here to extract the Human Subject Study Record Attachment](#)

## Study Record(s)

Attach human subject study records using unique filenames.

1) Please attach Human Subject Study 1

Add Attachment

Delete Attachment

View Attachment

## Delayed Onset Study(ies)

|  | Study Title | Anticipated Clinical Trial? | Justification   |
|--|-------------|-----------------------------|---|
|  |             | <input type="checkbox"/>    | <input type="text"/><br><p>Add Attachment Delete Attachment View Attachment</p> |